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(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SCIMED Place, Maple Grove, MN 55311-1566 (US).

(72) Inventor: VRBA, Anthony, C.; 12266 88th Place North, Maple Grove, MN 55369 (US).

(74) Agents: ARRETT, Oliver, F. et al.; Suite 2000, 6109 Blue Circle Drive, Minnetonka, MN 55343 (US).

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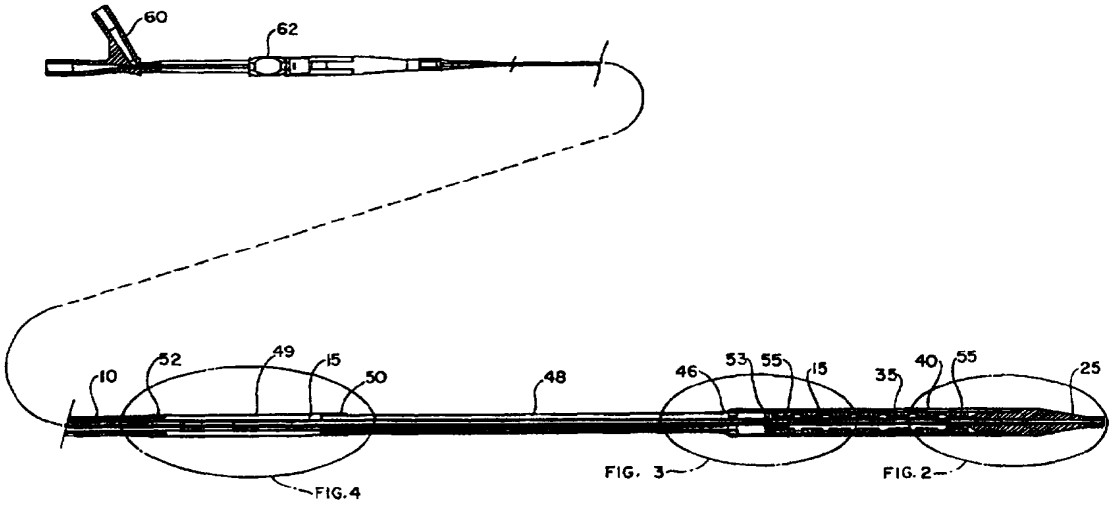

(57) Abstract

The present invention provides an improved stent delivery catheter. The stent delivery system comprises a catheter having a stent receiving portion adapted to receive a stent (35) near the distal end (25) of the catheter and a stent (35) concentrically arranged around the catheter within the stent receiving portion. The stent delivery system further comprises a proximal outer sheath (10), a retractable distal sheath (40) surrounding at least a portion of the stent (35) and containing the stent in its reduced delivery configuration and a pull back means (45) connected (46) to the retractable distal sheath (40, 48). The system further comprises an arrangement wherein the retractable sheath (48) is pulled into the catheter (49) when the pull back means is pulled proximally and the distal sheath is retracted, freeing the stent for delivery.

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STENT DEPLOYMENT CATHETER WITH RETRACTABLE SHEATH

Field of the Invention

This invention relates to a stent delivery catheter system, such as the kind used in percutaneous transluminal coronary angioplasty (PTCA) procedures. More particularly, it relates to a stent delivery catheter employing a retractable sheath which retracts within the catheter to release a self-expanding or balloon expandable stent.

Background of the Invention

In typical PTCA procedures, a guiding catheter is percutaneously introduced into the cardiovascular system of a patient and advanced through the aorta until the distal end is in the ostium of the desired coronary artery. Using fluoroscopy, a guide wire is then advanced through the guiding catheter and across the site to be treated in the coronary artery. An over the wire (OTW) balloon catheter is advanced over the guide wire to the treatment site. The balloon is then expanded to reopen the artery. The OTW catheter may have a guide wire lumen which is as long as the catheter or it may be a rapid exchange catheter wherein the guide wire lumen is substantially shorter than the catheter. Alternatively, a fixed wire balloon may be used. This device features a guide wire which is affixed to the catheter and cannot be removed.

To help prevent arterial closure, repair dissection, or prevent restenosis, a physician can implant an intravascular prosthesis, or a stent, for maintaining vascular patency inside the artery at the lesion. The stent may either be a self-expanding stent or a balloon expandable stent. For the latter type, the stent is often delivered on a balloon and the balloon is used to expand the stent. The self-expanding stents may be made of shape memory materials such as nitinol or constructed of regular metals but of a design which exhibits self expansion characteristics.

In certain known stent delivery catheters, a stent and an optional balloon are positioned at the distal end of the catheter, around a core lumen. The stent and balloon are held down and covered by a sheath or sleeve. When the distal

portion is in its desired location of the targeted vessel the sheath or sleeve is retracted in a proximal direction on the catheter to expose the stent. After the sheath is removed, the stent is free to self-expand or be expanded with a balloon.

In a stent deployment system which utilizes a retractable sheath one problem which is encountered is the interaction of the sheath and guide catheter upon retraction. The traditional way of dealing with this is to make the retractable sheath long enough so that it will be contained in the guide catheter at all times. This increases system profile, reduces flexibility and creates excess friction upon sheath retraction.

Summary of the Invention

The present invention provides an improved stent delivery system. The stent delivery system comprises in a preferred embodiment, a catheter having a proximal outer shaft, a stent receiving portion adapted to receive a stent near the distal end of the catheter, a retractable distal sheath concentrically arranged around the stent receiving portion and a pull back means operatively connected to the distal sheath. The catheter is further arranged so that the retractable sheath or a member connected thereto is pulled into the proximal outer shaft of the catheter during retraction of the distal sheath thereby freeing the loaded stent. The inclusion of the retractable sheath maintains a reduced system profile and provides good flexibility.

In the preferred embodiment of the invention the basic components of the catheter consist of a stent sheath, i.e., a cover means surrounding the stent at least in part but preferably fully, a pull wire arrangement or other pull back means, such as a hydraulic or screw arrangement or other means, a manifold with a slide mechanism, a relatively non-compressible inner shaft, an outer shaft, and two radiopaque marker bands. The stent is introduced to the body housed in a polymer sheath. The sheath is operatively connected to the manifold by a stainless steel pull wire or the like. The manifold contains a slide mechanism. Deployment is achieved by actuating the slide mechanism to retract the stent sheath thereby releasing the stent from the sheath. A non-compressible inner shaft creates a lumen for guide wire passage and fluid delivery. A multi-component outer shaft receives the sliding sheath interiorly while maintaining a fluid path between the manifold and sheath. Two radiopaque marker

bands rest underneath the stent. The marker bands are spaced to match the length of the stent providing a visual guide for accurate placement and deployment.

The multi-component outer shaft preferably consists of a polyimide stainless steel composite tube, a high density polyethylene (HDPE) proximal slide sheath, a distal HDPE dual lumen tube, and a HDPE stent sheath. The proximal slide sheath is bonded to the distal end of the composite outer tube. The stent sheath is bonded to the distal end of the dual lumen tube to form a retractable sheath means. The proximal slide sheath is sized in correspondence with the distal dual lumen tube to form a tolerance seal with the dual lumen tube. The proximal end of the dual lumen tube slides into the distal end of the proximal slide sheath to absorb the length of the stent means which is retracted when the stent sheath is moved to release the stent. Together, the dual lumen tube and the stent sheath form a retractable sheath means which is received interiorly of the outer body portion of the catheter, such as the outer shaft. This contrasts with other methods where a distal segment slides over the proximal segment or collapses to absorb a length of a retracting member.

The proximal slide sheath is stationary and is in effect an extension of the outer shaft. The distal dual lumen slides into the proximal slide sheath. The ledge formed by the outside diameter growth between the two shafts remains stationary in the anatomy once tracked to the lesion. Therefore, the ledge will not engage the anatomy during deployment. In the prior art, anatomy engagement with a sheath sliding over the proximal shaft is a distinct possibility, especially on a bend.

The distal segment's profile will be smaller with an "into" length change according to this invention compared to an "over" length change. A "collapsing" design requires a profile growth during deployment and can present a nonuniform profile when pulling the shaft back into the guide catheter.

The length of the absorbing member is minimized with an "into" or "over" design versus a "collapsing" design. Since a collapsing tube requires space even in it's collapsed position, the ratio between the required shaft length change and the absorbing member will never be one to one. The collapsing shaft's longer absorption member exposes the pull wire to buckle over a longer length. The axial length change in the pull wire caused by buckling could cause unintended stent deployment.

Other objects, features, embodiments and characteristics of the present invention, as well as the methods of operation and functions for the related elements of the structure, and the combination of parts and economics of manufacture, will become more apparent upon consideration of the following description with reference to the accompanying drawings, all of which form a part of this specification.

Brief Description of the Figures

Figure 1 shows a side view of a catheter according to the invention having a loaded stent including a cross-sectional view of the distal portion thereof and a side view of the proximal end of a catheter according to the invention showing the manifold portion thereof.

Figure 2 is a detail view of a portion of the catheter of Figure 1 according to the invention having a loaded stent.

Figure 3 is a detail view of a portion of the catheter of Figure 1 according to the invention having a loaded stent including a cross-sectional view of the retracting arrangement for the retractable sheath.

Figure 4 is a detail view of a portion of the catheter of Figure 1 showing the arrangement for retracting the sheath into the catheter.

Figure 5 is a cross-section view of the catheter outer shaft.

Figure 6 is a cross-section view of the catheter inner shaft.

Figure 7 is a cross-section view of the catheter proximal slide sheath.

Figure 8 is a cross-section view of the catheter distal dual lumen.

Detailed Description of the Invention

Figure 1 shows a longitudinal cross-section of a specific preferred embodiment of a stent delivery catheter that is the subject of the present invention. The device generally comprises a proximal outer shaft 10 of a predetermined length forming an outer body portion which covers the majority of the catheter excluding a portion of the distal end of the catheter. This outer shaft 10 is characterized by a flexible tube which contains room for a pull wire and a guide wire lumen. Preferably the outer shaft 10 is comprised of a polyimide and stainless steel ribbon composite material. The detail structure is shown in Figure 5 to be a tube formed of polyimide 10a formed around a

braided ribbon 10b as is known in the art. Affixed to the distal end of shaft 10 is proximal slide sheath 49 which serves as an extension of outer shaft 10 and to receive the retractable sheath means. The proximal outer shaft 10 and proximal slide sheath 49 encloses a guide wire lumen 15 which is longer than outer shaft 10 and extends through and beyond outer shaft 10 to terminate at the distal tip 25 of the catheter. Preferably the guide wire lumen 15 encloses a guide wire (not shown) which aids in the navigation of the catheter through the appropriate vessel. The guide wire lumen 15 is preferably made of flexible, but incompressible construction such as a polymer encapsulated braid or coil as shown in Figure 6. Such construction is known in the art. The flexibility of the braid/coil construction allows the catheter to navigate through body lumens and the incompressibility of the braid/coil aids in maintaining the integrity for the catheter and aids in deployment accuracy when the sheath is being retracted during stent release. The braid/coil may be comprised of stainless steel 15a, encased in a polymer such as polyimide 15b, with an inner layer of Teflon 15c.

Situated just proximal to the distal tip 25 which may be a body of urethane, is the portion of the catheter around which the stent 35 is concentrically carried. Distal tip 25 may be affixed to the catheter by an adhesive such as H.B. Fuller 3507, a urethane adhesvie, or the like. The stent 35 surrounds and is carried by the guide wire lumen 15. The stent 35 is preferably a nitinol alloy or mesh self-expanding stent, but may also be a balloon expandable stent carried by an expansion balloon. Self-expanding and balloon expandable stents are well known in the art and require no further description.

The present invention further comprises a retractable distal sheath 40 which covers and contains the loaded stent 35. The retractable distal sheath 40 will hold a self-expanding stent in its reduced delivery configuration. Alternatively, the retractable distal sheath may merely contain a balloon expandable stent which is positioned over an expansion balloon. The distal sheath 40 is connected to a retracting member 45 such as a pull wire by means of a pull collar 46 which is a ring-shaped member of stainless steel affixed to the interior of sheath 40 by an appropriate adhesive such as Loctite 4011, a cyanoacrylate. As best seen in Figure 3, collar 46 is slidably carried on guide wire lumen 15, which allows a physician to retract the distal sheath 40 from the proximal end of the catheter thus releasing the stent 35 in the

targeted area of the vessel. The retractable sheath 40 may be flexible or rigid, and is generally used to retain the stent 35 and protect the vessel wall. The retractable sheath is preferably formed of a material which provides tensile strength, but is flexible, such as polyethylene.

The proximal end of retractable sheath 40 is affixed to a dual lumen tubular member 48 at 49 by an appropriate adhesive such as H.B. Fuller 3507. Dual lumen member 48 is also shown in Figure 8 with large lumen 48a and smaller lumen 48b through which guide wire lumen 15 and pull wire 45 extend respectively.

The proximal end of member 48 is received within proximal slide sheath 49 at 50 in a sliding tolerance seal to allow retraction of member 48 into slide sheath 49 when the pull wire 45 retracts sheath 40, sheath 40 and dual lumen 48 comprising a retractable sheath means which is withdrawn into the catheter body. Utilizing a slide sheath 49 of polyethylene tubing having an inside diameter of .049 inches and a dual lumen tube 48 of HDPE having an outside diameter of .047 inches is an example of an arrangement which provides a tolerance fit. Slide sheath 49 is a simple cylinder in form as shown in Figure 7. The proximal end of slide member 49 is affixed by adhesive such as H.B. Fuller 3507 to outer shaft 10 at 52 and is a continuation of shaft 10 in effect to provide a two-piece or composite outer shaft.

A bumper member 53 is also carried on guide wire lumen 15 and is positioned at the proximal end of stent 35 as shown. Bumper 53 may be of polyethylene and is affixed to guide wire lumen 15 by adhesive such as H.B. Fuller 3507 so as to prevent movement of stent 35 in a proximal direction when sheath 40 is retracted.

Marker bands 55 are included to aid in positioning and maybe affixed to inner shaft 15 by adhesive such as Loctite 4011.

At the proximal end of the catheter is a manifold structure 60 with slide mechanism 62 as is known in the art. Slide 60 is connected to pull wire 45 in known manner for retracting the sheath 40 by moving the slide proximally.

To prepare the stent delivery catheter the stent 35 is compressed and loaded into the stent receiving portion and covered by protective distal sheath 40. The distal sheath 40 remains covering the underlying stent 35 during the placement of the stent 35 by the delivery catheter through the patient's vasculature. During the

placement of the stent 35, protective distal sheath 40 protects the patient's vasculature from the stent 35.

When in place, as the sliding member 46 is pulled back, the distal sheath 40 begins to retract. The stent is prevented from moving proximally with the sheath by the bumper 53 and therefore, the stent 35 begins to release and expand while the sheath begins to expose it. After the stent 35 is expanded and in place, the catheter is withdrawn. It should be understood that a balloon expandable stent could also be utilized by arranging the stent around an optional placement balloon (not shown). Once the sheath 40 is fully retracted the placement balloon would be inflated through its inflation lumen (not shown) to deploy the stent.

Preferably stent 35 is self expanding, such as a nitinol alloy stent, or it may be expanded by means of an internal balloon positioned under the stent 35 on the distal end of the inner core 40. Those skilled in the art will recognize other suitable materials and constructions which may be employed to serve substantially the same function.

It should be understood that other mechanical methods of retracting the pull back wire, besides the manifold apparatus disclosed herein, may be employed.

The present invention may be incorporated into both of the two basic types of catheters used in combination with a guide wire, commonly referred to as over-the-wire (OTW) catheters and rapid-exchange (RX) catheters. The construction and use of both over-the-wire and rapid-exchange catheters are well known in the art. The usable length of the delivery catheter is approximately 135 cm. For a rapid-exchange catheter the distance from where the guide wire accesses the guide wire lumen to the distal tip will be approximately 5 cm to 35 cm.

The above disclosure is intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

What is claimed is as follows:

1. A stent delivery system comprising:

a catheter and a stent carried by the catheter;

cover means surrounding the stent and constructed and arranged for retraction to expose the stent for release from the catheter;

the catheter being constructed and arranged to receive at least part of the cover means interiorly thereof upon retraction of the cover means.

2. A stent delivery system comprising:

a catheter body having a proximal end and a distal end;

a proximal outer body portion of the catheter extending distally and terminating before the distal end of the catheter to leave a stent mounting area;

a stent concentrically carried by the catheter at the mounting area;

retractable sheath means surrounding at least a portion of the stent;

pull back means operatively connected to the sheath for retracting it, and

wherein the distal end termination of the outer body portion is constructed and arranged to receive at least a proximal end portion of the retractable sheath means inside the body portion upon retraction of the sheath means.

3. A stent delivery system comprising:

elongate flexible catheter means comprised of an outer tube of predetermined length having proximal and distal ends and an inner tube of greater length, the inner tube being carried within the outer tube and extending beyond the distal end of the outer tube, the inner tube being relatively non-compressible;

a distal tube having proximal and distal ends and being received over the portion of the inner tube extending beyond the distal end of the outer tube, the proximal end of the distal tube being slidably received into the distal end of the outer tube, the distal end of the distal tube terminating proximally of the distal end of the inner tube to leave a mounting area for a stent on the inner tube;

manifold means and slide means arranged at the proximal ends of the outer and inner tubes;

a stent concentrically carried by the inner tube in the mounting area thereof;

a bumper carried by the inner tube and affixed to it at a position adjacent the proximal end of the stent;

a sheath concentrically arranged about the stent and having proximal and distal ends, the proximal end being affixed to the distal end of the distal tube;

pull means carried by the inner tube for movement thereon in a proximal direction, the means being positioned proximal of the bumper and interiorly affixed to the sheath near its proximal end;

pull wire means extending from the proximal end portion of the outer tube and therethrough and into and through the distal tube, the distal end of the wire means being connected to the pull means, the proximal end of the wire means being connected to the slide means whereby, upon movement of the slide means in a proximal direction, the pull wire means moves the pull means similarly to retract at least the proximal end portion of the distal tube into the distal end for the outer tube thereby initiating release of the stent from the catheter.

4. The delivery system of claim 3 wherein the pull means is in the form of a ring-like collar.

5. The delivery system of claim 3 wherein the outer tube is a two-piece construction comprised of a proximal portion and a distal portion affixed together, the distal portion receiving the dual lumen tube.

6. The delivery system of claim 5 wherein the proximal outer tube portion is of small outer diameter than the distal portion and the distal portion fits over the proximal portion for connection therebetween.

7. The delivery system of claim 3 wherein the distal tube is a dual lumen tube and one lumen fits over the inner tube, the other lumen receiving the pull wire.

AMENDED CLAIMS
[received by the International Bureau on 6 February 1998 (06.02.98); new claims 8-11 added; remaining claims unchanged (2 pages)]

a bumper carried by the inner tube and affixed to it at a position adjacent the proximal end of the stent;

a sheath concentrically arranged about the stent and having proximal and distal ends, the proximal end being affixed to the distal end of the distal tube;

pull means carried by the inner tube for movement thereon in a proximal direction, the means being positioned proximal of the bumper and interiorly affixed to the sheath near its proximal end;

pull wire means extending from the proximal end portion of the outer tube and therethrough and into and through the distal tube, the distal end of the wire means being connected to the pull means, the proximal end of the wire means being connected to the slide means whereby, upon movement of the slide means in a proximal direction, the pull wire means moves the pull means similarly to retract at least the proximal end portion of the distal tube into the distal end for the outer tube thereby initiating release of the stent from the catheter.

4. The delivery system of claim 3 wherein the pull means is in the form of a ring-like collar.

5. The delivery system of claim 3 wherein the outer tube is a two-piece construction comprised of a proximal portion and a distal portion affixed together, the distal portion receiving the dual lumen tube.

6. The delivery system of claim 5 wherein the proximal outer tube portion is of small outer diameter than the distal portion and the distal portion fits over the proximal portion for connection therebetween.

7. The delivery system of claim 3 wherein the distal tube is a dual lumen tube and one lumen fits over the inner tube, the other lumen receiving the pull wire.

8. The stent delivery system of claim 3 further comprising an expandable balloon coaxially mounted on the inner tube, the stent concentrically carried over at least a portion of the balloon.

9. A stent delivery system comprising:

a catheter body having a proximal end and a distal end;

a proximal outer body portion of the catheter extending distally and terminating before the distal end of the catheter to leave a stent mounting area;

a stent concentrically carried by the catheter at the mounting area;

a retractable sheath means for exposing the stent comprising a proximal end portion and a distal end portion surrounding at least a portion of the stent, a substantial portion of the proximal end portion of the retractable sheath means distal to the proximal outer body portion of the catheter with a relatively small portion of the proximal end portion of the retractable sheath means received within the outer body portion of the catheter;

a pull back means operatively connected to the retractable sheath for retracting the retractable sheath means, and

wherein the distal end of the proximal outer body portion is constructed and arranged to slidably receive at least the proximal end portion of the retractable sheath means inside the proximal outer body portion upon retraction of the retractable sheath means.

10. The stent delivery system of claim 9 wherein the pull back means comprises a wire.

11. The stent delivery system of claim 9 further comprising an expandable balloon coaxially mounted on the catheter, the stent concentrically carried over at least a portion of the balloon.

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Fig. 1

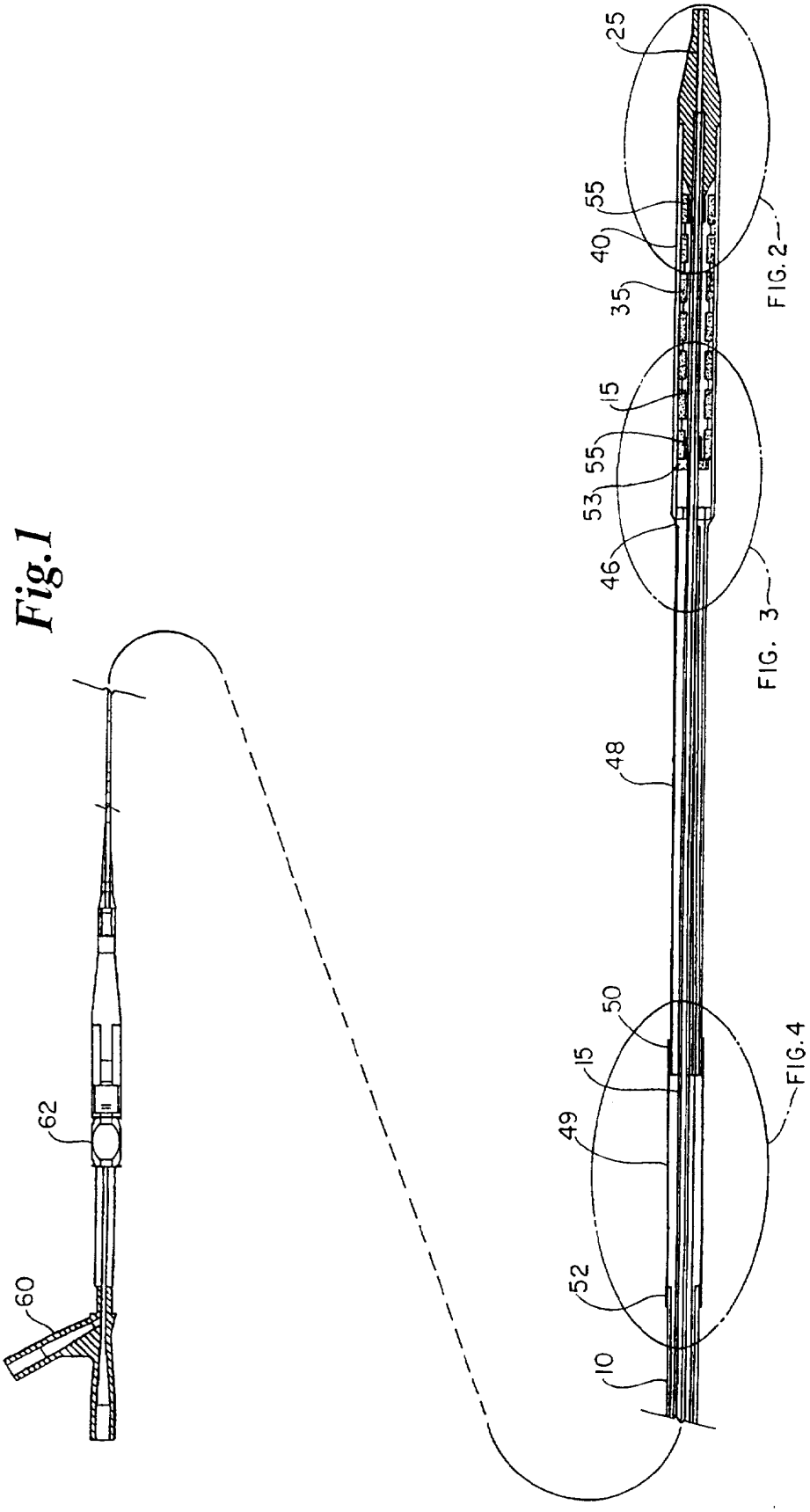


Fig.3

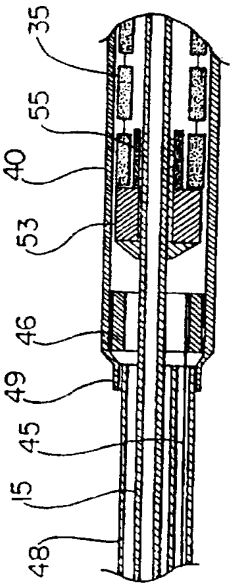


Fig.2

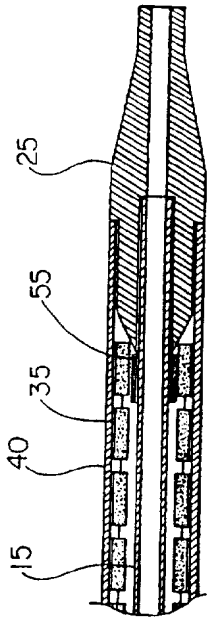


Fig.4

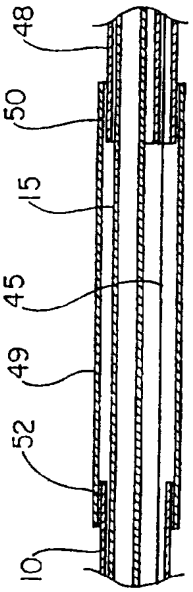


Fig.5

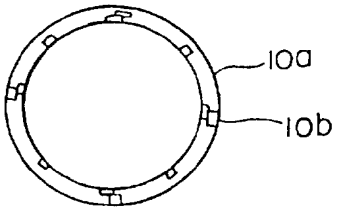


Fig.6

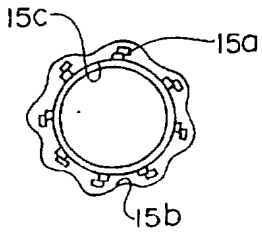


Fig.7

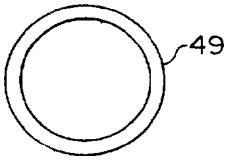
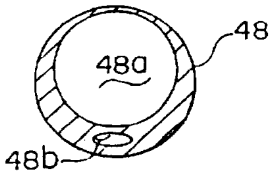


Fig.8



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/15057

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 534 007 A (ST. GERMAIN ET AL.) 9 July 1996	
A	US 5 201 757 A (HEYN ET AL.) 13 April 1993	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
27 November 1997	08/12/1997

Name and mailing address of the ISA	Authorized officer
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Information on patent family members

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